K130599

510K SUMMARY

JUN 5 2013

Submitter's name:	Koninklijke Utermöhlen N.V.
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Date of 510k special:	1 March 2013
Device Proprietary Name:	Wart Freeze
Device common or usual name:	OTC wart removal system
Classification name.	Cryosurgical unit, accessories
Classification code:	GEH
Regulation Number:	21 CFR 878.4350

Substantial equivalence / predicate devices (Confidential)
The following device listed in the table is predicate device based on technology, method of application and materials for this 510k Special.

Name of device	Manufacturer	Predicate comparison	510(k) Number	
Wart Freeze	Koninklijke Utermöhlen	Intended use, technology, materials	K101049	Primary predicate for changes

Description of the device:
Wart Freeze is a private label (private label trade mark: Wart Freezer, Cryogenic Wart Remover) over the counter cryosurgery product for the treatment of common and plantar warts. The device consists of the following:

- A pressurised dispenser (canister) containing as ingredient 38ml dimethylether (DME) with a polypropylene applicator that is permanently attached (fixed) to the dispenser. The gas does not harm the ozone layer. The applicator is used to administer the cryogen directly to the wart. The applicator is cleaned after each use.
- Disposable 70% alcohol cleansing swabs for cleaning the applicator after each use
- Instruction for use

Indications for use statement
Wart Freeze (private label trade mark: Wart Freezer, Cryogenic Wart Remover) is indicated for the removal of common and plantar warts.

Intended use
The wart remover product is intended to be used in adults and children 4 years of age and older.

Statement of technological characteristics of the device

a. The Wart Freeze (private label trade mark: Wart Freezer, Cryogenic Wart Remover) is a cryosurgical system comprised of a dispenser containing as ingredient, dimethylether (DME), and a permanently attached (fixed) applicator to apply the cryogen directly to the wart.

b. **Laboratory (functionality) testing** (CONFIDENTIAL)
The following testing was conducted:

1. Comparative laboratory testing using predicate devices using a phantom skin model. The predicates were used in accordance with their instructions. The functionality testing indicated that the various competitor products are similar in effectiveness.
2. Applicator temperature laboratory test using an infrared camera technology was conducted to determine the degree of cold generated by the cryogen on the applicator. The applicator surface at the tip of the applicator (part placed over the wart after dispensing the cryogen) is -50 ° C.
3. Dose technique testing using infrared (IR) camera technology to determine the dispensing freeze time between the two potential dose techniques, i.e., 3 short presses of the dispenser versus 3 long presses of the dispenser. The test also evaluated effectiveness of freeze time between the dose techniques. The effectiveness of 3-short presses resulted in a freeze time of 1.31 seconds versus 1.99 seconds for 3-long presses. The maximum acceptable concentration of DME administered was 0,37 mg/ml during both dose techniques as result of safety (dose) valve used.

c. Biocompatibility testing
Biocompatibility testing was performed on the applicator in line with ISO 10993:5 *Tests for in vitro cytotoxicity*. The test was conducted to determine the safety of the cryogen and applicator material, polypropylene. The applicator material when in contact with the cryogen was found to be non-lysic. (CONFIDENTIAL)

d. Chemical residual testing
Laboratory testing was conducted to assess and identify any potential chemical residuals including leachable or degradable components. The test concluded that there were no chemical residuals in the dimethylether/polypropyelene extracts whereby there is no leachable between the applicator and cryogen, dimethylether. (CONFIDENTIAL)

e. Inhalation studies on the dimethylether
Dimethylether inhalation studies were conducted by the suppliers. The US National Toxicological Programme (NTP) conducted acute toxicity studies (lethal dose (LC_{50})) on mouse and rabbit. The study concluded that DME did not produce acute toxicity in animal models or bacteria (genus: *Ames Salmonella Typhimiurium*). Developmental toxicity studies in animal models also showed that DME did not have any significant toxic effect on the mice or rabbit pups. There is however a limitation in the availability of human data when it comes to DME developmental and reproductive toxicity in human beings. DME received a ranking of not acutely toxic by the NTP. Current exposure limits for DME has been set at 1000 ppm or 0.1% DME for an 8-hour daily life-time exposure. Acute exposures for consumer products where DME is used have been shown to be in the range of 100 ppm for short

periods of time (<15 minutes/day). This is far below the levels to induce central nervous system effects. (CONFIDENTIAL)

f. Comparison to predicate devices

Application

The product administers cryogen directly onto the wart by way of an applicator permanently fixed to the dispenser.

Applicator effectiveness duration

The applicator maintains a temperature of -50 ° C. The effectiveness of predicates is identical.

Cryogen

The product uses 100% dimethylether, same as predicate device.

Safe/Ease of use

The design of the product incorporates the use of a safety valve. The dispenser is held upside down and actuated by pressing the bottom of the dispenser 3 times before the safety valve allows cryogen to be administered into the applicator and onto the wart. The predicate device has identical safety valve mechanism.

Indications for use

The product is indicated for over-the-counter treatment of common and plantar warts. The predicate device is indicated for identical intended use.

Conclusions

Based on the information presented above, it is concluded that the from the data supports the safety and effectiveness of the Wart Freezer. It is indicated that based on the safety data related to the ingredient, dimethylether, and similar labelling to the predicate device, this product should be qualified for the special 510k submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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Letter dated: June 5, 2013

Re: K130599
Trade/Device Name: Wart Freeze
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 29, 2013
Received: May 06, 2013

Dear Dr. Michael:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130599

Device Name, Wart Freeze

Indications For Use: The product is indicated for the removal of common and plantar warts.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part-21-CFR-801-Subpart-D) (21-CFR-801-Subpart-C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.06.06 12:10:19 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number __K130599_____